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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/019,966 | 05/01/2002 | Masataka Nadaoka | 2001-1915A | 6249 |

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| EXAMINER | |
|---|---|
| NGUYEN, BAO THUY L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/019,966 | NADAOKA ET AL. | |
| | Examiner | Art Unit | |
| | Bao-Thuy L. Nguyen | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10/27/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *34-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. The amendment dated 27 October 2005 has been received. Claims 28-33 have been cancelled. Claims 34-47 have been added and are pending.

2. All rejections not reiterated herein below are withdrawn in view of the cancellation of claims 28-33.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 38 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 38 and 45 recite methods using biosensors where marker reagents are held in a first part of a development portion such that only part of said marker reagent are elutable by a test sample. Such biosensors are not taught by the specification as originally filed.

In the event that Applicant believes support can be found, Applicant is respectfully requested to point to the page and line number where support can be found.

*Claim Rejections - 35 USC § 112*

5. Claims 34-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-47 are indefinite with respect to the use of unconventional claim language. Since these are method claims, it is recommended that action verbs, such as developing, measuring, detecting, etc, be used.

Claims 34 and 38 are vague and indefinite because the relationship between the components in the inspection target solution and the marker reagent has not been properly defined. Even though the claims recite that the marker reagent can be bonded to the measurement target (i.e. analyte), it is unclear if this complex then binds to the immobilized reagent forming a sandwich of sort. The relationship between the marker reagent and the immobilized reagent is also vague. The immobilized reagent is recited as binding to the analyte, however, it is unclear if the marker reagent and the analyte competes for binding to the immobilized reagent.

The claims are further vague with respect to the recitation of measuring in a "arbitrary position" because there is no clear guidance as to how or where the measurement is to be performed. Arbitrary is defined as "based on or subject to

individual judgment or preference", thus, this claims is vague and indefinite. It would provide clarity to the claims if an area between the first and second parts on the development portion be designated as the first measurement area, for example.

These claims recite a step of correcting the measured bonding amount of the marker reagent on the basis of the amount of marker reagent eluted from the development portion but are not immobilized in the second part of the development portion. However, it is unclear what exactly is involved in this correction? Is a ratio being taken, a difference or a total of the marker reagent?

Claims 41 and 45 are confusing because the relationship between the various reagents has not been clearly defined. For example, these claims recite that the marker reagent can be bonded to the immobilized reagent, and the immobilized reagent can be specifically bonded to said marker reagent; however, neither of these reagents are recited as binding to an analyte (i.e. a measurement target). How does measurement of the analyte occurs if nothing is binding to the analyte?

Claims 38 and 45 are confusing with respect to the recitation of "part of said marker reagent being elutable". It is unclear how the marker reagents are held in the first part of the development portion such that only some of it is elutable.

### *Response to Arguments*

6. Applicant's arguments submitted 27 October 2005 have been considered but are moot in view of the new ground(s) of rejection.

New claims 34-47 define over Delacroix and Kuo between these references do not teach a method where a measurement is taken of labeled reagents after sample has been added but before any complex is formed in a detection area.

*Conclusion*

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 3/18/06